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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/985,873

**Applicant(s)**

BURANDA ET AL.

**Examiner**

Ann Y. Lam

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, 16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14, 16 and 18-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

Claims 12, 13, 15, 17 and 28-53 are canceled.

Claims 1-11, 14, 16, 18-27 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 14 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Siiman et al., 5,945,293.

Siiman et al. disclose a device comprising:

a vessel (col. 16, line 47);

a plurality of sensor beads (col. 11, line 15) located within said vessel to form interstitial spaces therethrough, said plurality of sensor beads comprising at least two different types of beads, each of said types of beads being made of a material different from the material of any other of said types of beads (col. 11, lines 43-47); and

a plurality of biomolecules (col. 11, lines 15-18) bound to at least a portion of said plurality of beads, each of said biomolecules having a fluorescent tag (col. 26, lines 58-65), said plurality of biomolecules comprising at least two different kinds of

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biomolecules (col. 11, lines 15-18), each of said different kinds of biomolecules being bound to a respective type of said at least two different types of sensor beads (col. 11, lines 15-16),

wherein said sensing device comprises at least two sensing regions, each of said sensing regions including one of said at least two different kinds of biomolecules (two different regions each occupied by at least two particles with different biomolecules are located are considered to be the claimed two sensing regions).

As to claim 14, the device comprising at least two sensing regions, each of said sensing regions including one of said at least two different kinds of biomolecules (col. 11, lines 15-18).

As to claim 25, said sensor beads are coated with at least one coating of said plurality of biomolecules (col. 11, lines 15-18.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-10, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siiman et al., 5,945,293, in view of Wilding, 5,637,469.

Siiman et al. teach the invention substantially as claimed (see above).

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However, Siiman et al. do not disclose that the vessel has a width, depth and length as claimed by Applicant.

Wilding teaches a vessel (22) with a plurality of sensor beads (col. 14, lines 38-41) bound to a plurality of biomolecules ( col. 14, line 40). Wilding teaches that the mesoscale dimensions of the device provides the advantage of reducing the amount of sample required and enhancing the rate of reaction (col. 8, lines 5-13.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Siiman et al. vessel in the mesoscale dimensions as taught by Wilding because Wilding teaches that a smaller vessel provides the advantage of requiring less sample and enhancing rate of reaction.

As to the following claims, Wilding teaches the dimensions as follows.

As to claim 2, the vessel as a width of 250  $\mu\text{m}$  to 500  $\mu\text{m}$  (col. 2, lines 51-53.)

As to claim 4, the vessel has a depth of 50  $\mu\text{m}$  to 100  $\mu\text{m}$  (col. 2, line 55.)

As to claim 5, the channels are microfluidic (col. 2, lines 51-55).

As to claim 6, the microfluidic channels have a width of 10  $\mu\text{m}$  to 500  $\mu\text{m}$  (col. 2, line 53.)

As to claim 3, neither Siiman et al. nor Wilding disclose a vessel that has a specific length of 0.5 cm to 3.0 cm.

However, Wilding teaches that the length of a channel may be designed to permit the timed mixing and addition of sample and reagent components (col. 15, lines 20-22.) Wilding also teaches various embodiments having chambers of .5 cm (i.e., 5.2 mm lengths, col. 20, line 7, and col. 21, line 47.)

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It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Forming the length of the vessel containing beads to 0.5 cm to 3.0 cm provides a workable or optimum range for containing or mixing particular sample and reagent components, and thus discovering this workable or optimum range involves only routine skill in the art.

As to claim 27, Siiman et al. do not disclose that the interstitial spaces each has a volume of 1 nL to 1000 nL.

However, Wilding teaches that the volume of the detection chamber can be decreased to increase rate of reaction (col. 8, lines 16-20), and that the device may be microfabricated with microliter volumes, or nanoliter volumes or less, which advantageously limits the amount of sample and/or reagent fluids required for an assay (col.8, lines 23-27.)

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Forming the Siiman et al. device such that the interstitial spaces each has a volume of 1 nL to 1000 nL provides a workable or optimum range for a desired rate of reaction or amount of sample and reagent fluids required for an assay, and thus discovering this workable or optimum range involves only routine skill in the art.

As to claims 7-10, Siiman et al. do not teach the material comprising the vessel as claimed by Applicant.

However, Wilding teach that using a transparent material allows for optical detection. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Siiman et al. vessel of transparent material as taught by Wilding because Wilding teaches that transparent material provides the advantage of allowing optical detection.

As to the following claims, Wilding teaches the material as follows.

As to claim 7, the microfluidic channels are comprised of optically transparent material (col. 10, line 3; and col. 12, line 1; col. 7, lines 39, and lines 42-45.)

As to claim 8, the optically transparent material comprise glass (col. 7, line 39 .

As to claim 9, the optically transparent material comprise quartz (col. 7, line 39.)  
(Glass is made of quartz.)

As to claim 10, the optically transparent material comprises a polymer (i.e, plastic, col. 7, line 59.)

3. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siiman et al., 5,945,293, in view of Mian et al., 6,319,469.

Siiman et al. disclose the invention substantially as claimed (see above).

However, as to claim 22, Siiman et al. do not disclose that the vessel includes obstructive features therein for preventing flow of said sensor beads.

Mian et al. disclose a flow cytometry device (col. 23, line 25) including beads for the detection of molecules (col. 42, lines 46-48.) Mian further discloses that the beads are retained in a channel by a filter (col. 42, lines 48-49.) It would have been obvious to

one of ordinary skill in the art at the time the invention was made to provide a filter as taught by Mian et al. in the Siiman et al. flow cytometry device, because Mian et al. teach that the filter provides the advantage of retaining the beads.

As to claim 23, Siiman et al. also do not disclose that neighboring obstructive features of said obstructive features are located 5  $\mu$ m to 20  $\mu$ m from each other.

However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, locating obstructive features at the distance claimed by Applicant relates to optimum or workable ranges and thus its discovery involves only routine skill in the art.

4. Claims 18-21, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siiman et al., 5,945,293, in view of Kraus et al., 5,925,567.

Siiman et al. disclose the invention substantially as claimed (see above with respect to claim 1). However, Siiman et al. do not disclose spacer beads (claim 18), nor foundation beads (claim 19) within the vessel, nor beads having the specific diameter claimed (claims 21 and 24), nor biotin as the means to bind biomolecules to beads (claim 26).

Kraus teaches a device comprising a chamber containing beads having affinity to specific molecules for selective binding (col. 2, lines 32-34, and col. 5, lines 41-42.) As to claims 18 and 19, Kraus also teaches spacer beads comprising non-activated beads



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at the top, bottom or a specific region of a column or mixed with activated beads in order to reduce cell-to-cell interactions (col. 10, lines 42-45.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide spacer beads at the top, bottom or specific region of the Siiman et al. column or mixed with activated beads in the Siiman et al. column in order to reduce cell-to-cell interactions as taught by Kraus as would be desirable for more accurate results. (The spacer beads at the bottom of the column are considered foundation beads.)

As to claim 20, Kraus also teaches that the beads can be made of glass (col. 5, line 41.)

It would have been obvious to one of ordinary skill in the art to use glass as the material to form the beads as taught by Kraus in the Siiman et al. invention as a well known and conventional material used for forming beads as a solid support for binding to materials.

As to claims 21 and 24, Kraus teaches that the beads have a diameter of 250 to 550  $\mu\text{m}$ , and that such diameters allow flow of cells through the column and yet provide sufficient surface area to enable efficient cell interaction (col. 10, line 38.) (It appears that Kraus is referring to both spacer and sensor beads, see column 10, lines 33-45.)

It would have been obvious to one of ordinary skill in the art to form the Siiman et al. sensor and foundation beads such that it has a diameter of 250 to 550  $\mu\text{m}$  in order to allow for flow of cells through the column and yet provide sufficient surface area to

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enable efficient cell interaction as taught by Kraus, as would be desirable for more accurate results and easier usage.

As to claim 26, Kraus teaches biotin as the means to bind molecules to beads (col. 8, lines 64-66.) It would have been obvious to one of ordinary skill in the art to use biotin as the means to bind molecules to beads in the Siiman et al. device as taught by Kraus, as a well known and conventional means to bind molecules to beads.

### ***Response to Arguments***

Applicant's arguments filed March 28, 2006 have been fully considered but they are not persuasive. Applicant argues that Siiman et al. does not disclose at least two sensing regions, each of the sensing regions including a respective one of two different kinds of biomolecules, but rather than Siiman et al. indicates that there is one mixture and one measurement site. This argument is not persuasive because two different regions each occupied by at least two particles with different biomolecules are located are considered to be the claimed two sensing regions, each region including one of the at least two different kinds of biomolecules, as recited by Applicant. Thus Applicant's claims do not distinguish over this prior art.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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